K080401

510(k) Summary
for the AMT Interbody Fusion Devices

MAY – 9 2008

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the AMT Interbody Fusion Devices.

Date Prepared: February 12, 2008

1. **Submitter:**
Advanced Medical Technologies AG
Kasteler Strasse 11
66620 Nonnweiler-Braunhausen
Germany

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** SHELL/WAVE/LOOP Cages
Common Name: intervertebral body fusion device
Classification Name: intervertebral body fusion device - cervical
Intervertebral body fusion device - lumbar
21 CFR section 888.3080
ODP/MAX
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
   - BAK/C Vista Interbody Fusion - peek-optima lt1, Zimmer Spine, Inc (P980048 S003)
   - BRANTIGEN I/F CAGE, DePuy Spine Inc, (P960025)
   - PARAMOUNT INTERVERTEBRAL BODY FUSION DEVICE (K072120)

4. **Description of the device:**

The SHELL was especially adapted to the local anatomy in order to secure the surgical result as well as possible. Its caudal side is flat, its cranial side is domed and the implant is formed conically from anterior to posterior. In the lateral view, the implant has a slightly lordotic form. The A/P view is trapezoidal. There are x-ray pins at the four edges, which slightly protrude the cage in order to maximize rotational fixation.

The LOOP is a banana-shaped implant with optimized tip design and an integrated swivel joint for the instrument fixation. Both factors facilitate the implantation. The radial orientated fixation teeth define the direction of implantation and secure the implant position. LOOP is shaped with a 6° lordosis.

The WAVE is rectangular in shape. Cross section is trapezoidal with the lateral side 1mm higher than the medial. WAVE has a neutral and a 6° lordosis. The posterior end has a threaded hole for attaching insertion instruments, while the other end is solid and tapered. The WAVE cages are implanted in pairs.

Materials:
PEEK-OPTIMA LT1 polymer (ASTM F2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications)

Function:

The SHELL Cage was developed as an intercorporal implant for anterior cervical spondylodesis.

The WAVE Cage was developed as an implant for the posterior stabilization of the lumbar spinal column with the technique of Posterior Lumbar Interbody Fusion (PLIF).

The LOOP Cage was developed as an implant for the posterior stabilization of the lumbar spinal column with the technique of Transforaminal Lumbar Interbody Fusion (T-LIF).

Intended Use:

SHELL Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. SHELL Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. SHELL Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The WAVE/LOOP Cage is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. WAVE implants are to be used with autogenous bone graft and implanted via an open posterior approach. The WAVE Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

5. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
   The AMT Interbody Fusion devices have the same indications and material, and similar designs as previously cleared devices.

6. **Summary of Nonclinical Tests**
   Tests performed according to ASTM F2077/F2267 indicate that the AMT Interbody Fusion devices meet required mechanical strengths. Some of the predicate devices have a different geometry than the AMT Interbody Fusion devices and do not have some test results reported in their PMA summaries, therefore, additional acceptance values for testing will be utilized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

Advanced Medical Technologies, AG
% Mr. J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681

Re: K080401
Trade/Device Name: SHELL, WAVE and LOOP Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, ODP
Dated: February 12, 2008
Received: February 14, 2008

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080401

Device Name: WAVE Cage

Indications for Use:

The WAVE Cage is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. WAVE implants are to be used with autogenous bone graft and implanted via an open posterior approach. The WAVE Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mtn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080401

Indications for Use

510(k) Number (if known): K080401

Device Name: LOOP Cage

Indications for Use:

The LOOP Cage is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. LOOP implants are to be used with autogenous bone graft and implanted via an open posterior approach. The LOOP Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark P Ogden for mam

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080401

Indications for Use

510(k) Number (if known): K080401

Device Name: SHELL Cage

Indications for Use:

SHELL Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. SHELL Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. SHELL Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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